THAT WHICH IS CLAIMED:

1. A pharmaceutical composition for the treatment and/or prophylaxis of disease associated with fibrosis in a vertebrate, said composition comprising at least one activin antagonist, and optionally a pharmaceutically acceptable carrier, adjuvant and/or diluent.

2. The pharmaceutical composition of claim 1, wherein the activin antagonist is follistatin, or a fragment(s) or analogue thereof.

3. The pharmaceutical composition of claim 2, wherein the follistatin is a single chain protein comprising between 288 and 315 amino acids with a molecular weight of between about 30,000 and 60,000 Daltons as estimated by SDS-PAGE in the absence of reducing agents, derived from follicular fluid and able to inhibit the secretion of follicle-stimulating hormone (FSH).

4. The pharmaceutical composition of claim 2, wherein the follistatin is a single chain protein classified as NCBI (National Center for Biotechnology Information) protein XP_003891, AAH04107.

5. The pharmaceutical composition of claim 2, wherein the follistatin or a fragment(s) or analogue present in the pharmaceutical composition exists in a form selected from the group consisting of: follistatin/chelate, follistatin/drug, follistatin/prodrug, follistatin/toxin and follistatin/detector group and follistatin/imaging marker.

6. The pharmaceutical composition of claim 1, wherein the activin antagonist is follistatin-related protein or a fragment(s) or analogue thereof.

7. The pharmaceutical composition of claim 6, wherein the follistatin-related protein has a sequence as defined in Genbank accession number NP_005851.

8. The pharmaceutical composition of claim 1, wherein the activin antagonist is an antibody raised against activin.

9. The pharmaceutical composition of claim 8, wherein the activin to which the antibody is raised is activin A, activin AB or activin B.

10. The pharmaceutical composition of claim 8, wherein the activin to which the antibody is raised is a heterodimer or homodimer of mature inhibin β_A or β_B subunit chains free of inhibin α chain.

11. The pharmaceutical composition of claim 10, wherein the two subunits comprise between 110 and 120 amino acids with molecular weights of about 12,000 - 13,000 Daltons as estimated by SDS-PAGE in the absence of reducing agents.

12. The pharmaceutical composition of claim 10, wherein the activin contains β_A subunit with sequence as defined in GenBank accession number M13436 and/or β_B subunit with sequence defined in GenBank accession number M13437.

13. The pharmaceutical composition of claim 1, wherein the activin antagonist is a compound which interferes with activin binding to its respective receptor.

14. The pharmaceutical composition of claim 13, wherein said compound is an antibody raised against the activin receptor.

15. The pharmaceutical composition of claim 14, wherein the activin receptor to which the antibody is raised is ActRIIA or ActRIIB or ActRIA or ActRIB or ALK2 or ALK4.

16. The pharmaceutical composition of claim 13, wherein the compound is an antibody raised against receptor for a protein selected from the group consisting of: activin A, activin AB and activin B.

17. The pharmaceutical composition of claim 13, wherein said compound is a Smad signalling molecule selected from Smad6 and Smad7 or fragment(s) or analogue(s) thereof.

18. The pharmaceutical composition of claim 13, wherein said compound is a molecule that specifically inhibits TGFβ/activin type I receptors.

19. The pharmaceutical composition of claim 18, wherein said compound is selected from triarylimidazole analogues.

20. The pharmaceutical composition of claim 19, wherein said compound is SB-431542.

21. The pharmaceutical composition of claim 1, wherein the disease associated with fibrosis is one of: a hyperproliferative or inflammatory fibrotic disease; a pulmonary fibrosis; an inflammatory bowel disease, or a related condition such as ulcerative colitis or Crohn's Disease; or liver fibrosis or cirrhosis.

22. The pharmaceutical composition of claim 1, wherein the disease associated with fibrosis is liver fibrosis or cirrhosis.

23. A process for preparing the pharmaceutical composition of claim 1, wherein said process comprises homogeneously mixing at least one activin antagonist with a pharmaceutically acceptable carrier, adjuvant and/or diluent.

24. A method for the treatment of disease associated with fibrosis in a vertebrate in need of said treatment, wherein said method comprises administering to said vertebrate, a therapeutically effective amount of at least one activin antagonist.

25. A method for the treatment of disease associated with fibrosis in a vertebrate in need of said treatment, wherein said method comprises administering to

said vertebrate, a therapeutically effective amount of the pharmaceutical composition of claim 1.

26. The method of claim 24, wherein the vertebrate is selected from the group consisting of human, non-human primate, mice, cattle, sheep, goats, horses, rabbits, birds, cats and dogs.

27. The method of claim 26, wherein the vertebrate is human.

28. The method of claim 24, wherein the disease associated with fibrosis is one of: a hyperproliferative or inflammatory fibrotic disease; a pulmonary fibrosis; an inflammatory bowel disease, or a related condition such as ulcerative colitis or Crohn's Disease; or liver fibrosis or cirrhosis.

29. The method of claim 24, wherein the disease associated with fibrosis is liver fibrosis or cirrhosis.

30. A method for screening for a disease associated with fibrosis in a vertebrate comprising:

(a) contacting a sample from the vertebrate with an antibody (or fragment thereof) raised against an activin polypeptide (or fragment or analogue thereof);

(b) detecting the presence of the antibody (or fragment thereof) bound to the activin polypeptide; and

(c) comparing the amount of bound antibody to the amount bound in a reference sample, and diagnosing a disease associated with fibrosis in said vertebrate, wherein a change in the amount of bound antibody in the sample compared to the reference sample is indicative of disease.

31. A method for screening for a disease associated with fibrosis in a vertebrate comprising:

(a) contacting a sample from the vertebrate with an antibody (or fragment thereof) raised against a follistatin polypeptide (or fragment or analogue thereof);

(b) detecting the presence of the antibody (or fragment thereof) bound to the follistatin polypeptide; and

(c) comparing the amount of bound antibody to the amount bound in a reference sample, and diagnosing a disease associated with fibrosis in said vertebrate, wherein a change in the amount of bound antibody in the sample compared to the reference sample is indicative of disease.

32. A method for screening for a disease associated with fibrosis in a vertebrate comprising:

(a) contacting a first aliquot of a sample from the vertebrate with an antibody (or fragment thereof) raised against an activin polypeptide (or fragment or analogue thereof);

(b) detecting the presence of the antibody (or fragment thereof) bound to the activin polypeptide; and

(c) contacting a second aliquot of a sample from the vertebrate with an antibody (or fragment thereof) raised against a follistatin polypeptide (or fragment or analogue thereof);

(d) detecting the presence of the antibody (or fragment thereof) bound to the follistatin polypeptide; and

(e) comparing the amount of activin-bound antibody to the amount of follistatin-bound antibody, and comparing the relative difference to that found in a reference sample, and diagnosing a disease associated with fibrosis in said vertebrate, wherein a change in the relative ratio of activin- and follistatin-bound antibody in the sample compared to the reference sample is indicative of disease.

33. The method of any one of claims 30 to 32, wherein the reference sample is obtained from a vertebrate not suffering from a disease associated with fibrosis.

34. The method of any one of claims 30 to 32, wherein the sample within which the method of screening is performed is a plasma or tissue sample, and involves standard histological and immunohistochemical techniques.

35. The method of any one of claims 30 to 32, wherein the disease associated with fibrosis is one of: a hyperproliferative or inflammatory fibrotic diseases; a pulmonary fibrosis; an inflammatory bowel disease, or a related condition such as ulcerative colitis or Crohn's Disease; or liver fibrosis or cirrhosis.

36. The method of any one of claims 30 to 32, wherein the disease associated with fibrosis is liver fibrosis or cirrhosis.

37. A diagnostic kit for the detection of a disease associated with fibrosis in a vertebrate, said kit comprising at least an antibody (or fragment thereof) raised against activin (or fragment thereof), together with a diagnostically acceptable carrier and/or diluent.

38. A diagnostic kit for the detection of disease associated with fibrosis in a vertebrate, said kit comprising at least an antibody (or fragment thereof) raised against follistatin (or fragment thereof), together with a diagnostically acceptable carrier and/or diluent.

39. The kit of claim 37 or 38, which comprises the following containers:

(a) a first container containing at least the antibody (or fragment thereof), and;

(b) a second container containing a conjugate comprising a binding partner of the antibody (or fragment thereof), together with a detectable label.

40. A diagnostic kit for the detection of disease associated with fibrosis in a vertebrate, said kit comprising at least: an antibody (or fragment thereof) raised against follistatin (or fragment thereof), together with a diagnostically acceptable carrier and/or diluent; and an antibody (or fragment thereof) raised against activin (or fragment thereof), together with a diagnostically acceptable carrier and/or diluent.

41. The kit of claim 40 which comprises the following containers:

(a) a first container containing at least an activin antibody (or fragment thereof), and;

(b) a second container containing at least a follistatin antibody (or fragment thereof);

(c) a third container containing a conjugate comprising a binding partner of the activin antibody (or fragment thereof), together with a detectable label, and

(d) a fourth container containing a conjugate comprising a binding partner of the follistatin antibody (or fragment thereof), together with a detectable label.

42. A method of gene therapy for the treatment of disease associated with fibrosis in a vertebrate, wherein said method comprises:

(a) inserting a nucleic acid molecule encoding for an activin antagonist, or fragment(s) or analogue thereof, or a vector comprising a nucleic acid molecule encoding for an activin antagonist or a fragment(s) or analogue thereof, into a host cell;

(b) expressing the nucleic acid molecule in the transformed cell.

43. The method of claim 42, wherein the activin antagonist is follistatin or fragment(s) or analogue thereof.

44. A method of gene therapy for the treatment of disease associated with fibrosis in a vertebrate, wherein said method comprises:

(a) inserting a nucleic acid molecule which is antisense for a fragment of a nucleic acid molecule encoding for activin, an activin receptor, or other activin-associated transduction pathway molecule, or fragment(s) or analogue thereof, or a vector comprising a nucleic acid molecule antisense for a nucleic acid molecule encoding for activin or a fragment(s) or analogue thereof, into a host cell.

(b) expressing the nucleic acid molecule in the transformed cell; and

wherein the expressed antisense nucleic acid molecule binds to the complementary nucleic acid molecules encoding activin, activin receptor or other activin-associated transduction pathway molecule thereby inhibiting the transcription or expression thereof.

45. The method of claim 44, wherein the antisense nucleic acid molecule is selected from the following:

a nucleic acid molecule that is antisense for at least a portion of the nucleic acid sequence encoding activin A, activin AB or activin AB;

a nucleic acid molecule that is antisense for at least a portion of the nucleic acid sequence encoding an activin receptor selected from ActRIIA or ActRIIB or ActRIA or ActRIB or ALK2 or ALK4;

a nucleic acid molecule that is antisense for at least a portion of the nucleic acid sequence encoding smad 2 or smad 3.

46. A method of gene therapy for the treatment of disease associated with fibrosis in a vertebrate, wherein said method comprises:

inserting a nucleic acid molecule which is mutated form of a nucleic acid molecule encoding for activin, or fragment(s) or analogue thereof, or a vector comprising a nucleic acid molecule which is a mutated form of the nucleic acid molecule encoding for activin or a fragment(s) or analogue thereof, into a host cell;

wherein the mutated activin-encoding nucleic acid molecule integrates into the host cell's native activin-encoding sequence by homologous recombination, thereby resulting in either no or incorrect transcription of the activin sequence, or expression of a mutated activin which does not bind to native activin receptors or interferes with normal activin-signalling.

47 The method of claim 46, wherein the activin-encoding sequence is a polynucleotide as defined in GenBank entry, accession number M13436 and/or M13437.

48. A method of gene therapy for the treatment of disease associated with fibrosis in a vertebrate, wherein said method comprises:

inserting a nucleic acid molecule which is a mutated form of a nucleic acid molecule encoding for an activin receptor, or fragment(s) or analogue thereof, or a vector comprising a nucleic acid molecule which is a mutated form of the nucleic acid

molecule encoding for an activin receptor or a fragment(s) or analogue thereof, into a host cell;

wherein the mutated form of the nucleic acid molecule encoding for an activin receptor or a fragment(s) or analogue thereof integrates into the host cell's native activin receptor-encoding sequence by homologous recombination, thereby resulting in either no or incorrect transcription of the activin receptor sequence, or expression of a mutated activin receptor which does not bind the native activin or interferes with activin-signalling.

49. The method of claim 48, wherein the activin receptor-encoding sequence is a polynucleotide encoding one of the following receptors: ActRIIA or ActRIIB or ActRIA or ActRIB or ALK2 or ALK4.